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Notice of Allowability

Application No.

10/699,502

Applicant(s)

WU ET AL.

Examiner

Susan Hanley

Art Unit

1651

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to 3/29/07.
2. ☒ The allowed claim(s) is/are 1,4,13,15,18,20 and 21.
3. ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 - a) ☐ All b) ☐ Some* c) ☐ None of the:
 1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

* Certified copies not received: _____.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.

THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.

4. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.
 5. ☐ CORRECTED DRAWINGS (as "replacement sheets") must be submitted.
 - (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached
 - 1) ☐ hereto or 2) ☐ to Paper No./Mail Date _____.
 - (b) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date _____.
- Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).
6. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

Attachment(s)

- | | |
|--|--|
| 1. <input type="checkbox"/> Notice of References Cited (PTO-892) | 5. <input type="checkbox"/> Notice of Informal Patent Application |
| 2. <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 6. <input checked="" type="checkbox"/> Interview Summary (PTO-413),
Paper No./Mail Date <u>20070329</u> . |
| 3. <input type="checkbox"/> Information Disclosure Statements (PTO/SB/08),
Paper No./Mail Date _____ | 7. <input checked="" type="checkbox"/> Examiner's Amendment/Comment |
| 4. <input type="checkbox"/> Examiner's Comment Regarding Requirement for Deposit
of Biological Material | 8. <input type="checkbox"/> Examiner's Statement of Reasons for Allowance |
| | 9. <input type="checkbox"/> Other _____ |

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DETAILED ACTION

Response to Amendment

Applicant's request for reconsideration of the finality of the rejection of the last Office action is persuasive and, therefore, the finality of that action is withdrawn.

The amendment and remarks filed 3/8/07 have been entered.

Claims 1, 3, 4, 13, 15, 17, 18, 20 and 21 are pending and under examination.

EXAMINER'S AMENDMENT

An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the issue fee.

Authorization for this examiner's amendment was given in a telephone interview with Wendy Davis on 3/29/07.

The application has been amended as follows:

Claims 3 and 17 were canceled.

Claim 1 was replaced by the following:

-- 1. A reagent system for substantially lysing red blood cells in a whole blood sample prior to leukocyte analysis, the reagent system comprising:

(a) a first reagent for substantially lysing the red blood cells in the whole blood sample, wherein the first reagent includes a saponin compound, an acid selected from the group consisting of a halogenated carboxylic acid, a phosphoric acid and a combination thereof, and an additional surfactant selected from the group consisting of a non-ionic surfactant, a cationic surfactant and a combination thereof, wherein the first reagent is autoclaved at about 121 °C; and

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(b) a second reagent for quenching the activity of the first reagent, wherein the second reagent includes a base and has a pH value of about 8 to about 12. --

The dependency of claim 4 was from "3" to -- 1 --.

Claims 13 was replaced by the following:

-- 13. A method of lysing red blood cells and stabilizing white blood cells present in a whole blood sample, the method comprising the steps of:

(a) combining a predetermined portion of the whole blood sample with a predetermined portion of a first reagent to substantially lyse the red blood cells in the whole blood sample, wherein the first reagent includes a saponin compound, an acid and an additional surfactant selected from the group consisting of a non-ionic surfactant, a cationic surfactant and a combination thereof, wherein the first reagent is autoclaved at about 121 °C; and

(b) quenching the lysing action of said first reagent by the addition of a predetermined portion of a second reagent to result in a solution containing leukocytes and substantially lysed red blood cells and having a pH value of about 3 to about 6, wherein the second reagent includes a base and has a pH value of about 8 to about 12. --

The dependency of claim 18 was changed from "17" to --13 --.

Claim 20 was replaced by the following:

-- 20. A method of preparing a whole blood sample for leukocyte analysis, comprising the steps of:

(a) substantially lysing red blood cells in at least a portion of the whole blood sample by adding a saponin compound, an acid and an additional surfactant selected from the group consisting of a non-ionic surfactant, a cationic surfactant and a combination thereof, to the sample to form a mixture, wherein said saponin compound, acid and additional surfactant are autoclaved together at about 121 °C; and

(b) substantially quenching the mixture by bringing the pH value of the mixture to about 3 to about 6. --

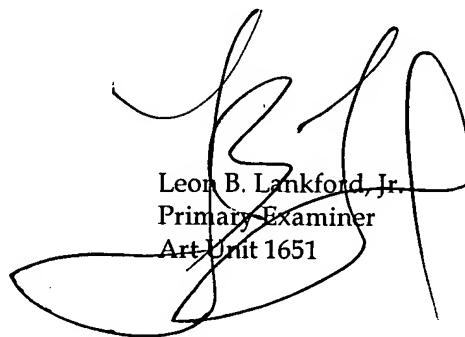
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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Susan Hanley whose telephone number is 571-272-2508. The examiner can normally be reached on M-F 9:00-5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Wityshyn can be reached on 571-272-0926. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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Art Unit 1651